

RETHINK "SAFE AND EFFECTIVE"

#### 1. FLAWED STUDIES

Vaccine manufacturers conduct their own vaccine safety studies, and <u>they</u> are flawed. **Not one vaccine clinical trial** has ever used a true inert-placebo control group. Instead, studies have used 1) no control group, 2) control groups receiving other vaccines (themselves approved without placebo), or 3) control groups receiving a vaccine ingredient (such as <u>aluminum</u>) as "placebo."

### 2. SHORT SAFETY REVIEW PERIODS

Vaccines are classified as biologics. As such, the safety review periods are allowed much shorter duration than safety review periods for traditional pharmaceutical drugs - sometimes <u>as little as days or weeks</u> compared to years for traditional drugs. For example, the safety review period for the two Hepatitis B vaccines on the market are: <u>4 days</u> for Engerix-B & <u>5 days</u> for Recombivax HB.



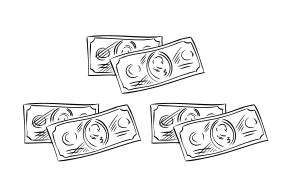
### 3. NO MANUFACTURER LIABILITY

In the 1986 National Childhood Vaccine Injury Act (NCVIA), Congress gave economic immunity to pharmaceutical companies for injuries/deaths caused by vaccines. It removed liability from vaccine manufacturers due to high injury claims. The law states, "No vaccine administrator or manufacturer may be made a party to a civil action... for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988." -42 U.S.C.§§300aa-11

# 4. FAILURE OF GOVERNMENT TO PROTECT

The 1986 Act left manufacturers with no incentive for creating safe vaccines. Attempting to monitor safety, the Act mandated the Dept. of Health & Human Services to study vaccine safety & provide biennial reports to Congress (Mandate for Safer Childhood Vaccines). HHS has **not filed a single report in over 30 years** (ICAN v. HHS).

# 5. VACCINE INJURY PAYOUTS



Over \$5.2 billion has been paid out since 1986 for vaccine injuries and death through the National Vaccine Injury Compensation Program (NVICP). A three-year Harvard Medical School review of VAERS (Vaccine Adverse Events Reporting System) estimates less than 1% of adverse events are even reported, so the \$5.2 billion payout likely represents an extremely small number of vaccine injuries/death.